

**UNITED STATES DEPARTMENT OF COMMERCE****Patent and Trademark Offic**Address: COMMISSIONER OF PATENTS AND TRADEMARKS
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/308,830 08/04/99 SCHLIEVERT

P 600.346USWO

HM12/1003

EXAMINER

MERCHANT & GOULD P.C.
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LEE, L

ART UNIT

PAPER NUMBER

15

1645

DATE MAILED:

10/03/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/308,830	Applicant(s) Schlievert et al
	Examiner LI Lee	Group Art Unit 1645

Responsive to communication(s) filed on Jul 26, 1900

This action is FINAL.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

- Claim(s) 1, 3-9, 12-14, and 17-29 is/are pending in the application.
 Of the above, claim(s) _____ is/are withdrawn from consideration.
 Claim(s) _____ is/are allowed.
 Claim(s) 1, 3-9, 12-14, and 17-29 is/are rejected.
 Claim(s) _____ is/are objected to.
 Claims _____ are subject to restriction or election requirement.

Application Papers

- See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
 The drawing(s) filed on _____ is/are objected to by the Examiner.
 The proposed drawing correction, filed on _____ is approved disapproved.
 The specification is objected to by the Examiner.
 The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 All Some* None of the CERTIFIED copies of the priority documents have been
 received.
 received in Application No. (Series Code/Serial Number) _____
 received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- Notice of References Cited, PTO-892
 Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
 Interview Summary, PTO-413
 Notice of Draftsperson's Patent Drawing Review, PTO-948
 Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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DETAILED ACTION

1. Applicant's amendment filed on July 26, 2000 (Paper Number 13) has been received and entered. Claims 2, 10-11, and 15-16 have been canceled, claims 1, 3-9 have been amended, and new claims 19-29 (not 19-31 as applicant states on the amendment page 3) have been added, consequently claims 1, 3-9, 12-14, and 17-29 are pending in the instant application.
2. The rejection of claims 1-14 and 17-18 under 35 U.S.C. 112, second paragraph, as being indefinite for using the terms "mutant SPE-A toxin", "wild type SPE-A toxin", the recitation of the positions of substituted amino acid in the mutant SPE-A toxin, and "substantially nonlethal", "substantially corresponding" is maintained and applied to newly added claims 19-29 for the reasons set forth in the office action mailed on 1/18/00 and below.

In response to applicant's argument that the specific protein sequences related to these terms can be found in the sequence of Figure 3 as well as the attached sequence listing, it is noted that the sequence upon which applicant relies are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. Without reciting a specific amino acid sequence, one cannot make the mutant SPE-A toxin which has specific mutations in the pyrogenic exotoxin A (SPE-A toxin) due to the existence of other pyrogenic exotoxin A (SPE-A toxin) (see Mascini EM et al, J Clin Microbiol, 37 (11): 3469-74, 1999) and one of ordinary skill in the art would not be able to locate the specifically claimed mutations in a SPE-A toxin.

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In response to applicant's argument that the term "substantially nonlethal" or "substantially corresponding" is described and defined in the specification, it is noted that the descriptions upon which applicant relies are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims.

3. The rejection of claims 1-4, 6, 8, 10, 12-14, and 17-18 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for single, double, and triple mutant of speA toxin, N20D, C87S, C90S, K157E, S195A, K16N, D45N, N20D/C98S, N20D/K157E, AND N20D/D45N/C98S, respectively, and the method for protecting an animal or reducing symptoms administering the mutants, does not reasonably provide enablement for any mutant of speA toxin or other toxin which is substantially nonlethal is withdrawn in view of applicant's amendment.

4. The rejection of claims 1-2, 12-14, and 17-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Hartwing et al (International Immunology 5 (8), 869-875, 19993 in Form 1449) is withdrawn in view of applicant's amendment.

5. Claims 1-2, and 12-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Kaller et al. (J Exp Med 175:387, Feb 1992 in Form 1449) is withdrawn in view of applicant's amendment.

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6. Claims 1-3, 6, 8, and 12-14 and 17-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Okonogi et al (US 4,172,126, Oct 23, 1979) is withdrawn in view of applicant's amendment.

7. Claims 1-6, 8-10, and 12-14 are rejected under 35 U.S.C. 102(a) as being anticipated by Kline et al (Infection and Immunity 64 (3), 861-869, Mar 1996 in Form 1449) is withdrawn in view of applicant's amendment.

8. The rejection of claims 1, 3-14, and 17-18 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11, 14-19, 22-23 of copending Application No. 08/973391 is maintained. Applicant states that this rejection will be addressed when it becomes absolute.

Status of Claims

9. No claims are allowed. All claims stand rejected.

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1645 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Li Lee whose telephone number is (703) 308-8891. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (703) 308-3909.

Li Lee
September 27, 2000


LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600